

家蚕丝素蛋白基医卫纺织材料的 改性策略与应用进展

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摘 要:家蚕丝素蛋白(silk fibroin, SF)是一类提取自蚕茧的天然长纤维结构蛋白,具有良好的生物相容性、低免疫原性、可控降解性及可加工与可功能化修饰等优势,是医卫纺织材料的重要候选生物基原料。梳理了家蚕SF的分子结构与理化特性,概述了其在丝腺中的形成过程及再生SF的制备与提取方法,总结了SF基医卫纺织材料的关键改性策略并归纳其在组织工程、药物递送、医用防护与智能医疗等方向的功能化应用与研究进展,指出SF基材料从实验室研究向临床与产品转化仍面临诸多挑战,包括安全性与长期体内评价不足、制备工艺与质量控制标准缺乏、规模化生产一致性与成本控制困难,以及监管路径与应用场景匹配不清等问题。展望未来,随着材料改性技术与临床转化体系的不断完善,SF基医卫纺织材料有望在替代部分传统合成材料、推动材料绿色化与智能化发展方面实现更广泛的应用。

关键词:医卫纺织材料;丝素蛋白;生物材料;改性策略;功能应用

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Modification strategies and application progress of *Bombyx mori* silk fibroin-based medical and hygiene textile materials

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Abstract: *Bombyx mori* silk fibroin (SF) is a naturally derived long-fibrous structural protein extracted from silkworm cocoons, which has advantages such as favorable biocompatibility, low immunogenicity, controllable biodegradability, processability, and functional modification, making it an important candidate bio-based raw material for medical and hygiene textile materials. The molecular architecture and physicochemical characteristics of *Bombyx mori* SF were summarized, and its *in vivo* formation in the silk gland and the preparation and extraction methods for regenerated SF were described. The key modification strategies for SF-based medical and hygiene textile materials, and functional applications and recent progress in tissue engineering, drug delivery, medical

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protection, and intelligent hygiene systems were summarized. It was pointed out that the translation of SF-based materials from laboratory studies to clinical and commercial applications remain hindered by numerous challenges, including insufficient safety and long-term *in vivo* evaluation, the lack of manufacturing process and quality-control criteria, difficulties in consistency and controlling costs in large-scale production, and unclear alignment between regulatory pathways and application scenarios. Looking ahead, as material modification technologies and clinical translation frameworks continue to mature, SF-based medical and hygiene textile materials are expected to be applied more broadly in replacing certain traditional synthetic materials and driving the green and intelligent development of materials.

Keywords: medical and hygiene textile material; silk fibroin; biomaterial; modification strategy; functional application

医卫纺织材料的加工与利用是生物医学工程与纺织科学交叉融合的重要研究方向之一。该类材料不仅需要具备传统纺织材料所要求的力学性能与加工可行性,还需满足良好的生物相容性与生物安全性,以及可根据临床场景实现抗菌、防黏附、促血管生成或组织修复等特定功能^[1]。目前,临床与产业中广泛应用的医卫纺织材料主要包括棉等天然纤维和聚乳酸、聚氨酯等合成高分子纤维^[2]。然而,天然纤维和合成高分子纤维普遍存在生物活性不足、降解产物可能诱发细胞毒性反应以及与人体的动态匹配性有限等问题,制约了其在高端医用领域的进一步应用^[3]。

家蚕(*Bombyx mori*)是人类最早驯化的经济昆虫之一,其主要经济产物蚕丝因优良的综合性能在纺织领域享有“纤维皇后”之美誉。丝素蛋白(silk fibroin, SF)是蚕丝的主要结构成分,其相关产品已获得美国食品药品监督管理局(Food and Drug Administration, FDA)批准用于临床^[4]。SF具备良好的生物相容性^[5]、较低免疫原性^[6]、可控降解性^[7]及良好的加工成型与功能化修饰潜力^[8]。依托上述特性并结合多样化的结构调控与改性策略,SF基医卫纺织材料的应用已由早期的基础医用防护与创面敷料,逐步拓展至组织工程支架、可穿戴生物医学系统及药物递送等前沿研究领域。本研究以“SF的结构与提取—材料改性策略—功能化应用—挑战与展望”为主线,系统梳理了SF基医卫纺织材料在医疗与卫生领域的最新研究进展,重点阐述了其应用前景,指出了其在临床转化阶段面临的挑战与对应的解决方案,旨在为SF基医卫纺织材料的研究

与转化应用提供参考,推动其在医疗卫生领域绿色化与智能化发展。

1 家蚕丝素蛋白概述

1.1 丝素蛋白结构及特性

家蚕幼虫在五龄末期停止食桑,发育成熟的绢丝腺利用体内积累的营养物质,合成并组装丝蛋白,随后在吐丝过程中分泌并固化,形成蚕茧。家蚕蚕丝主要由SF和丝胶蛋白(silk sericin, SS)构成,位于内层的SF纤维约占总质量的70%~80%,外层包裹并发挥黏结与保护作用的SS约占总质量的20%~30%。SF富含甘氨酸(Gly)、丙氨酸(Ala)、丝氨酸(Ser)和酪氨酸(Tyr)等氨基酸,其主体由3种蛋白质组成:SF重链(fibroin heavy chain, Fib-H)、SF轻链(fibroin light chain, Fib-L)和Fibrohexamerin糖蛋白^[9]。其中,Fib-H由交替排列的疏水结晶区与亲水非结晶区构成,因此呈现典型的两亲性结构特征。鉴于Fib-H约占SF总质量的92%,其结构对SF材料的性能具有决定性影响。Fib-H疏水结晶区富含 $(\text{Gly-Ala-Gly-Ala-Gly-Ser})_n$ 和 $(\text{Gly-Ala/Ser/Tyr})_n$ 等重复序列结构^[10-11],易经自组装形成反平行 β -折叠为主的晶区结构,从而主导SF基材料的力学性能与结构稳定性^[12]。

1.2 天然和再生丝素蛋白的性质及制备

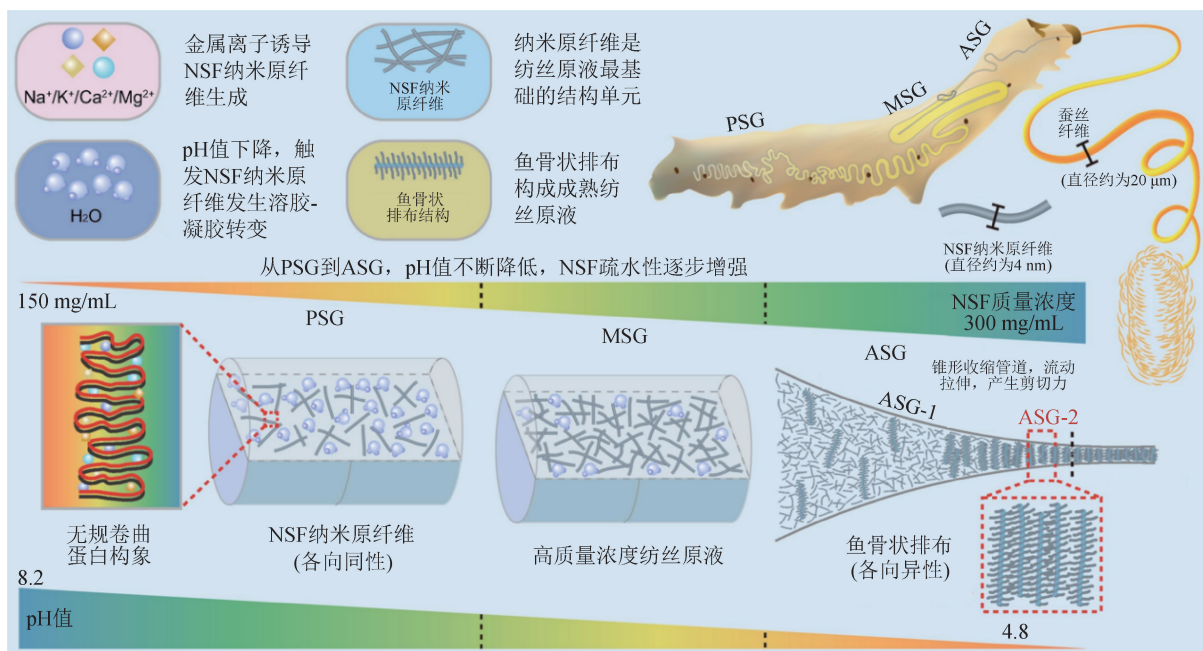
天然SF与再生丝素蛋白(regenerated silk fibroin, RSF)代表了家蚕SF在原生纺丝体系与体外再溶解-再构筑体系中的2种典型状态。天然SF存在于丝腺与蚕茧中,由家蚕纺丝系统合成,可实现

多尺度自组装,其结构高度有序、力学性能优异,但水溶性差、形态可塑性有限,因此主要作为高强度纤维材料使用,或作为后续加工的原料。相较之下,RSF 是利用化学或物理方法将天然 SF 溶解并经再生处理而得到的产物,其分子构象、结晶度与聚集形态可在一定范围内调控,且加工成形方式多样、溶液可操作性好,因此在组织工程、药物递送等生物医用领域应用更为广泛。

1.2.1 天然丝素蛋白的形成

在家蚕丝腺腔中,天然 SF 质量浓度为 150~300 mg/mL,性能稳定,未发生明显聚集沉淀^[13-15];在体外环境中,SF 易由无规卷曲等非晶构象向 β -折叠结构转变,导致蛋白聚集与沉淀^[16]。丝腺腔内 SF 的基础结构单元与组装方式,长期以来主要存在液晶模型^[17]与胶束模型^[18]两类观点。近年来的研究为液晶模型提供了更直接的试验数据支持。

Yang 等^[19]指出 SF 分子在水溶液中并非以孤立单链形式存在,而是呈现出由不规则的无序分形网络向高度取向结构演变趋势,该结构演变被认为是纤维成形的重要前提。Song 等^[20]基于金属离子与 pH 值梯度等生理因素的调控机制,阐释了天然 SF 由纳米纤维逐步演变为鱼骨状结构的多尺度自组装过程(图 1),为昆虫纺丝机制解析及高性能纤维的仿生设计提供了重要启示。Ma 等^[21]进一步结合单细胞和空间转录组学技术,绘制了家蚕幼虫五龄末期丝腺细胞的时空转录组图谱,从分子调控层面加深了对丝蛋白(包括 SF 和 SS)高效合成与分泌过程的理解。尽管上述工作推动了对天然 SF 形成机制的认识及其仿生应用探索,但由于原生纤维形态可塑性较差且功能化修饰受限,在医卫纺织材料研究中常采用结构和性能更易调控的 RSF 体系^[20]。



NSF—天然 SF; ASG—前部丝腺; ASG-1—前部丝腺近端段(上游段); ASG-2—前部丝腺远端段(下游段); MSG—中部丝腺; PSG—后部丝腺。

图 1 家蚕纺丝过程示意^[20]

Fig. 1 Schematic of *Bombyx mori* spinning^[20]

1.2.2 再生丝素蛋白的提取

RSF 的制备通常遵循“脱胶—溶解—透析—澄清/纯化”的基本流程^[22-23]。由于 SS 在体内应用中可能引发不良免疫反应或炎症,影响长期组织相容性,因此充分去除蚕丝中的 SS 是丝素蛋白基医卫纺

织材料实现医学应用的重要前提^[24]。脱胶旨在去除包裹于 SF 外层的 SS,常用方法包括碱性煮沸、中性皂处理、酶解脱胶以及超声/微波辅助脱胶等。蚕丝在 0.02~0.05 mol/L 的 Na_2CO_3 溶液中煮沸 30~60 min,丝胶去除率可超过 85%。该操作方法具有成

本低廉、操作简便等优势,因此在实验室中应用广泛^[25]。图2展示了天然蚕丝经0.05 mol/L的 Na_2CO_3 溶液煮沸50 min脱胶前后的表面形貌照片。中性皂(如马赛皂)脱胶相对温和,可更好地保持SF分子的完整性,但成本较高,且将SS作为副产物加以利用时,回收处理相对复杂^[26];酶解脱胶(如木瓜蛋白酶、胰蛋白酶、真菌蛋白酶)在有效去除SS的同时,

能较好地保护SF主链的完整性并保留其天然生物活性,适用于制备高质量RSF^[27-28];此外,超声/微波辅助技术可加速SS的去除,提高脱胶效率,并在一定程度上降低对SF的损伤^[29-30]。脱胶条件直接影响SF的相对分子质量分布与表面官能团的去留,进而决定其后续溶解性及最终材料性能。因此,必须根据目标应用与实际需求,选择并优化脱胶方案^[29]。

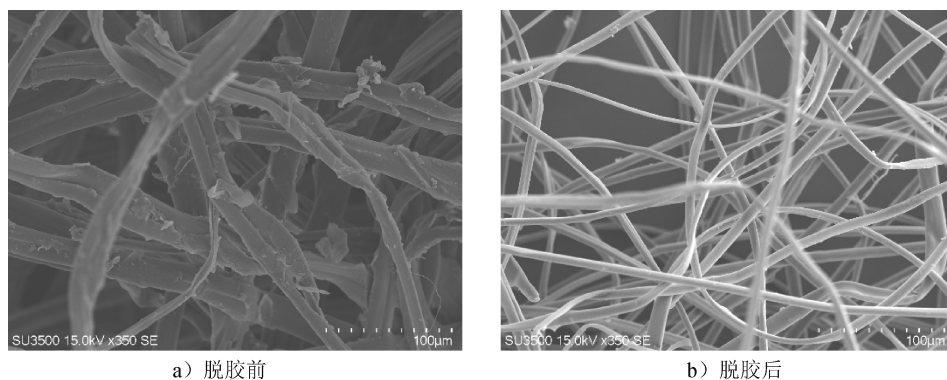


图2 脱胶前后蚕丝纤维表面形貌对比

Fig. 2 Surface morphology comparison of silk fibers before and after degumming

SF经溶解、透析和澄清/纯化处理得到可加工的RSF溶液。SF的溶解通常采用高浓度的盐溶液或三元溶剂体系,通过削弱分子间氢键等相互作用实现溶解^[31],典型体系包括9.3 mol/L的溴化锂溶液^[32]和日本学者Akiyoshi Ajisawa发明的三元溶剂(CaCl_2 -乙醇-水)^[33]。近年来,部分离子液体(如1-丁基-3-甲基咪唑鎓氯盐, $[\text{BMIM}]\text{Cl}$)因溶解效率高、可回收和相对环保等特点,也被用于SF的溶解与加工研究^[34]。溶解后的SF溶液通常经透析去除小分子盐与溶剂,再通过离心澄清获得均一的RSF溶液。该溶液可在4℃条件下短期储存,并有效维持溶液的稳定性与生物活性。

2 家蚕丝素蛋白的主要改性策略

SF的改性通常指通过物理、化学或分子改良的方法调控其聚集态结构、分子构象及表面界面特性,以获得满足特定应用需求的力学、降解与生物功能。目前,SF的物理改性策略在规模化生产中具备一定的生产可行性;化学修饰策略可赋予SF多种优异特性;SF的分子改良技术研究虽起步较晚,但其凭借极佳的体内生物安全性,在生物医药领域极具应用

潜力。

2.1 物理改性策略

物理改性多借助相对温和的外部条件调控SF的聚集与结晶结构,通常不引入额外化学试剂,这有利于在一定程度上保留其生物相容性。典型方法包括乙醇处理、热处理或pH值调控等,可诱导SF由无规卷曲等非晶构象向 β -折叠结构转变,从而提高材料的力学强度与结构稳定性^[35]。目前电喷雾、静电纺丝等成熟技术已用于SF基复合材料的规模化生产^[36-37]。

此外,通过机械拉伸、定向静电纺丝等方法调控微/纳米纤维的排列方向,可构建具有各向异性拓扑特征的取向纤维支架,促进轴突延伸或成肌细胞定向排列,为各向异性组织工程支架设计提供支撑^[38]。SF还可分别与还原氧化石墨烯、银纳米线、羟基磷灰石等功能性纳米材料复合,被赋予导电性、抗菌活性或骨诱导/骨传导活性,从而用于导电敷料或骨修复构建体的构筑^[39-41]。

值得注意的是,SF亦可介导生物矿化过程:其酸性氨基酸残基(如天冬氨酸、谷氨酸)可通过静电作用与配位作用富集并固定 Ca^{2+} ,促进羟基磷灰石或碳酸钙的成核与生长;同时,SF的多级结构(β -折

叠结晶区与原纤取向)有助于引导无机晶体的定向排列与组装,形成类骨有机-无机复合材料,从而拓展其在组织工程、药物递送等生物医学方向的应用^[42]。

2.2 化学修饰策略

化学修饰的核心在于利用 SF 分子侧链上的可反应官能团实现共价接枝与交联,以增强其细胞黏附能力、改善其界面相容性、赋予其靶向功能等^[43]。常用方法包括碳二亚胺偶联与二醛介导反应(如戊二醛交联),可将精氨酸-甘氨酸-天冬氨酸(RGD)序列^[44]、透明质酸^[45]及叶酸^[46]等生物活性分子引入 SF 基体,以提升材料的亲水性并增强细胞-材料的相互作用。例如:RGD 序列可与细胞膜表面的整合素受体结合,促进细胞黏附、铺展及细胞骨架重组;透明质酸可通过与分化簇 44(cluster of differentiation 44, CD44)等受体相互作用增强特定细胞对材料的识别能力,并调控其黏附、迁移等行为;叶酸修饰则利用叶酸受体介导的特异性结合与内吞,提高材料对叶酸受体高表达细胞的靶向能力。因此,化学修饰不仅能够调节 SF 材料的表面亲水性和界面性质,还可通过特异性分子识别调控细胞黏

附、铺展、迁移及细胞摄取等过程,为组织工程和靶向递送等应用提供功能基础。

此外,通过共价接枝等方式将多酚^[47]、壳聚糖^[48]、谷胱甘肽^[49]等具有抗氧化活性的功能性物质引入 SF,利用其所含酚羟基、氨基、羟基或巯基等活性官能团参与自由基清除或氧化还原反应,可赋予 SF 一定的抗氧化能力,有助于缓解氧化应激微环境,并促进慢性创面修复与组织再生。酶催化的酚类交联亦可用于制备凝胶化动力学与力学性能可调的可注射 SF 水凝胶,并保持较好的生物相容性^[50-52]。Cui 等^[53]探究了丝素蛋白水凝胶交联机制,主要包括辣根过氧化物酶/过氧化氢(HRP/ H_2O_2)酶促交联与钌/过硫酸钠(Ru/SPS)可见光光氧化还原交联两类体系(图 3)。该研究通过构建 Ru/SPS 可见光光氧化还原交联体系,依托丝素蛋白固有的酪氨酸残基氧化偶联形成二酪氨酸共价键,实现对丝素水凝胶的快速制备。相较于 HRP/ H_2O_2 酶促交联,该体系的凝胶化速率更快,可实现超高密度细胞的包埋。所获水凝胶交联网络更加均一,能够有效抑制 β -折叠构象的自发转变,保持力学性能的长期稳定。

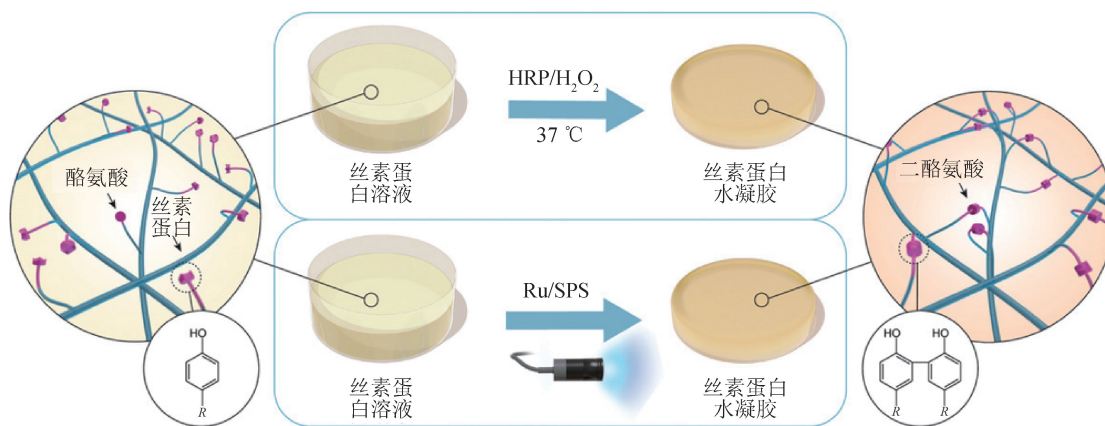


图 3 丝素蛋白水凝胶交联机制示意^[53]

Fig. 3 Schematic of cross-linking mechanism of silk fibroin hydrogel^[53]

化学修饰不仅能赋予 SF 多种优良特性,也能推动 SF 基材料的产业化进程,如甲基丙烯酸改性(如甲基丙烯酸缩水甘油酯、甲基丙烯酸酐等)能显著提升 SF 的力学性能,且原料成本可控^[54-55]。该方法引入可光交联基团后,可简化加工流程,适合规模化生产^[55-56]。

2.3 分子改良技术

基于家蚕转基因与基因组编辑等分子改良技术,可实现外源 DNA 在家蚕基因组中的定点插入或替换,对内源 SF 和 SS 基因进行定向调控与敲除^[57-58]。研究表明,通过外源蛋白高效表达或内源丝蛋白的精准重构,研究者已能从转基因家蚕茧中获得功能性遗传修饰丝素蛋白。

例如, Wang 等^[59]构建了高效家蚕丝素生物合成系统(Fib-H^{EXP}),通过优化 Fib-H 启动子和终止子,以及信号肽、连接肽等功能蛋白,实现了红色荧光蛋白与葡萄糖氧化酶在丝腺中的高效合成与分泌。其中,红色荧光蛋白在蚕丝中的质量占比可达 7.86%,且能保持天然蛋白的空间结构与生物活性。进一步地,基于该系统获得的葡萄糖氧化酶遗传修饰 SF 可构建抗菌 SF 水凝胶,通过催化糖尿病患者创面高浓度葡萄糖生成 H₂O₂,可有效抑制细菌感染并降低局部葡萄糖浓度,加速感染性创面愈合。Yu 等^[60]通过转录激活因子样效应物核酸酶介导的丝蛋白重链替换系统,将大壶状腺蜘蛛丝蛋白 2(major ampullate spidroin 2, MaSp2)与袋蛾丝素蛋白(eumeta variegata fibroin heavy chain, EvFibH)编码基因精准替换家蚕内源 Fib-H 基因;在纯合转化家蚕茧层中, MaSp2 与 EvFibH 占茧丝总蛋白的质量比分别达到 51.02%与 63.77%,所得遗传修饰 SF 纤维韧性分别提高 86%与 80%,结晶度均提升约 40%,显著突破天然家蚕丝的力学性能上限。除结构蛋白可实现替换外,外源基因编码的猫干扰素^[61]和人睫状神经营养因子^[62]等也已在蚕茧中实现表达。值得强调的是, Long 等^[63]通过优化外源蛋白序列并剔除冗余内源结构域,降低不利修饰的影响,在 SF 表达体系中实现高活性外源功能蛋白的稳定表达,从而显著提升融合蛋白的活性与稳定性。总体而言,分子改良技术能从内部优化 SF 的多种性能并赋予 SF 各种新功能,但复杂改性(如重组蛋白表达)可能增加生产成本,故需评估性能提升的边际效益^[23,54]。

3 多功能 SF 基医卫纺织材料的应用

近年来,凭借优良的理化与生物学特性, SF 在生物医学领域展现出广阔的应用潜力^[64]。总体而言, SF 基材料在体内表现出良好的生物相容性与较低的免疫原性。利用静电纺丝等技术构建的 SF 基三维多孔支架,可有效促进细胞黏附、迁移与增殖^[65]。部分 SF 基材料还具备抗菌^[66]与抗血栓^[67]特性。应用于外科缝合线等医用材料时,其可控降解性与组织相容性有助于减轻异物反应并降低术后感染风险^[68]。在药物递送方面, SF 可通过结构调

控与功能化修饰精准调节药物的负载与释放行为,并构建 pH 响应递送体系,如 pH 响应型 SF 基纳米颗粒在模拟胃部环境(pH 值=1.2)中性质稳定,可有效避免药物突释,在模拟肠道环境(pH 值=6.8)中逐渐释放药物,可实现靶向消化道给药^[69]。

3.1 医用防护材料

SF 凭借其良好的生物相容性、可降解性及结构可调控性,为突破传统合成防护材料(如聚丙烯、聚乙烯)难以兼顾防护效能与佩戴舒适性的技术瓶颈提供了新路径。通过静电纺丝与复合纺丝等加工方式,可构建兼具高效阻隔性能、抗菌性、亲肤性与透气性的 SF 基防护材料,在口罩滤材、医用防护服等场景中展现出重要应用价值。

Hossain 等^[70]通过酸水解与机械剪切制备 SF 纳米纤维网络,并与不锈钢网复合制备口罩材料。该材料对粒径为 0.3、0.5 和 1.0 μm 颗粒物的过滤效率分别可达 91.4%、95.4%和 98.3%,呼吸阻力为 92 Pa,在维持高过滤效率的同时显著降低了呼吸阻力,且兼具一定的自消毒能力与环境可降解性。Wang 等^[71]以 SF 缝合线为载体,通过表面改性负载黄连素与青蒿素,实现了长达 42 d 的稳定缓释,能持续发挥抗菌与抗感染作用,有效降低了缝合线相关感染风险。Zhang 等^[72]采用交替静电纺丝-电喷雾技术构建的 3 层 Janus 浸润性防护膜,对 PM_{2.5} 的过滤效率约 98.1%,同时采用具有形状记忆特性的热塑性聚氨酯组分可适应人体运动形变,兼顾了机械顺应性与透气舒适性。

3.2 创面修复敷料

创面修复是 SF 基医卫纺织材料中较为成熟的应用方向之一。SF 可被加工成薄膜、复合膜、水凝胶或海绵等形态,用于覆盖创面或构建人工皮肤替代物,且 SF 及其加工材料经功能改性后,可进一步实现抗菌、保湿、抗感染与促进组织再生等多重功能^[73]。

Fu 等^[74]以 SF 为基体开发 Janus 黏附敷料。动物实验显示,其对猪皮的黏附强度可达 94.46 kPa, 21 d 后瘢痕宽度仅 0.62 mm,且可促进创面菌群趋于平衡。Mao 等^[75]通过共价交联制备的胶原/SF/氢氧化镁复合海绵敷料,在感染创面模型中可显著降低感染并促进血管新生,同时在出血模型中表现出良好的止血与机械支撑协同效应。Chen 等^[76]构

建了 SF 原位快速成膜水凝胶敷料。该敷料约在 100 s 内可形成稳定凝胶膜,兼具透气、防水与可移除性,在全层皮肤缺损模型中可促进血管生成与毛囊再生,并有效减轻瘢痕形成。此外,进一步引入表皮生长因子^[77]、胰岛素样生长因子-1^[78]或银纳米颗粒^[79]等功能组分,可强化水凝胶敷料促血管生成、抗感染及炎症调控能力,为复杂创面修复提供新策略。

3.3 组织工程支架

组织工程技术通过构建三维支架、递送细胞并调控局部微环境,实现了受损组织结构与功能的协同修复^[80-82]。除皮肤组织修复外,SF 基材料凭借良好的力学性能、生物相容性、可降解性与加工灵活性,已被广泛用于骨、软骨、神经、肌腱及血管等多类组织的再生修复^[83]。

Liu 等^[84]采用“定向冷冻-机械压实-乙醇退火”工艺构建了仿生跟腱 RSF 支架,在纳米尺度诱导 β -折叠结晶、微米尺度形成单一取向结构,并增强宏观孔壁结合力,支架抗拉强度达 7.8 MPa,可有效促进肌腱再生。Liu 等^[85]采用空气等离子体刻蚀技术对 SF 电纺支架进行纳米图案化(即通过等离子体刻蚀在电纺纤维表面构建纳米尺度的岛状拓扑结构)。刻蚀 10 min 所得支架在保持约 90% 力学性能的同时,能显著增强间充质干细胞的黏附、增殖与成骨分化。另有研究以 RSF 为基体构建了负载肝细胞生长因子(hepatocyte growth factor, HGF)与成纤维细胞生长因子-4(fibroblast growth factor 4, FGF-4)的复合支架。该支架可在 16 d 内持续释放 HGF 和 FGF-4,并通过激活磷脂酰肌醇 3-激酶/蛋白激酶 B 信号通路促进脂肪间充质干细胞成肝分化,植入体内后可有效减轻急性肝衰竭模型中的炎症反应并促进组织重建^[5]。总体而言,SF 基支架在多组织再生修复中展现出较高潜力与临床转化价值^[86-87]。

3.4 药物递送系统

药物递送系统旨在提升药物稳定性、生物利用度与组织靶向性,以克服传统治疗在药代动力学、系统毒性及组织穿透性等方面的局限^[88-90]。依托生物相容性、结构可调控性与功能化修饰潜力,SF 基医卫纺织材料已发展出适用于口服^[7]、注射^[91]、黏膜给药^[92]与植入式^[93]等多种形式的药物递送系统。

SF(主要是 Fib-H)交替排列的亲水/疏水结构及其可构建的多孔结构,使其可同时包载亲水与疏水药物,并在一定程度上兼具较高的载药量与良好的结构稳定性^[93]。通过调控 β -折叠含量、交联密度与复合比例,可实现持续缓释或脉冲释放等可控释放行为^[94-95]。此外,SF 可构建刺激响应型载体,在 pH 值、温度、活性氧或酶等微环境信号的触发下实现位点特异性递送^[91]。SF 具备较好的水相加工特性,可依托再生 SF 水溶液,在以水为主要介质的温和条件下完成药物负载、材料组装及载体成型等过程,能够减少有机溶剂的使用及残留,有利于保持所负载生物活性成分的稳定性,在口服和黏膜递送体系的构建方面具备一定优势。在 SF 中引入靶向配体、成像分子或多酚类等功能组分,可构建集治疗、诊断与靶向功能于一体的多功能递送平台^[47,96-97]。还可对 SF 开展功能化改性,改性策略主要包括引入特异性配体、聚乙二醇化、负载药物分子、调控表面电荷、引入肿瘤标志物、引入荧光探针、引入表面官能团等^[98]。

3.5 其他应用方向

在环保卫生领域,SF 因其生物降解性与天然抗菌特性,可被加工成包装材料或抗菌材料,这为替代传统不可降解塑料、缓解环境污染提供了新路径。例如,Choi 等^[99]通过模板介导缠结工艺,以 SF 为原料制备了医用级可持续生物塑料(medical-grade and sustainable bioplastic, MSB),旨在替代牙科领域广泛使用的难降解一次性塑料正畸器具。研究表明,该材料兼具满足正畸需求的良好柔韧性与黏弹性,可实现正畸力的精准传递,还表现出优异的抗菌性能,可有效抑制口腔微生物生长。更为重要的是,MSB 支持闭环回收利用,可利用甲酸破坏模板与 SF 间的氢键实现结构解缠,再经乙醇选择性沉淀即可回收高纯度的 SF 与模板材料,回收后的 SF 仍可重构为结构稳定的状态,且力学性能与原始材料相近。

此外,SF 基医卫纺织材料在智能传感与柔性电子领域同样展现出巨大的应用潜力^[100]。在个性化医疗与数字健康技术快速发展的驱动下,SF 逐渐成为柔性生物电子学与生理传感领域的基础材料。SF 基医卫纺织材料兼具柔韧性、透气性、导电性可调及生物降解性等优势,基于此已构建多种功能化传感体系,如将 SF 与石墨烯、MXene 或碳纳米管复

合制备的导电丝织物和传感器,可实现对温度、湿度及生物电信号的稳定检测^[101-104];可穿戴 SF 基应变传感器凭借其良好的皮肤贴合性和信号稳定性,可实时监测呼吸、脉搏及关节运动等生理参数^[101,105-106];基于 SF 的温湿度响应型传感平台已被用于汗液成分分析及体表温度监测,为代谢状态评估与环境适应性分析提供了新思路^[104]。除体表传感外,超薄 SF 基神经接口材料因其优异的皮层贴合性,可用于皮层脑电图信号采集与神经调控,显著改善长期植入条件下的生物整合性与信号记录保真度^[107-108]。

4 挑战与展望

目前,医卫纺织材料在产业化和临床转化方面取得了一些进展,但多数产品仍无法标准化、规模化推广使用。如德国 Biotronik 公司在 2016 年推出的全球首款生物可吸收镁合金冠脉支架 Magmaris,已获得欧洲共同体认证(CE 认证),并在我国海南博鳌乐城国际医疗旅游先行区特许临床使用,但该支架仍存在腐蚀快速、降解过快和生物相容性不稳定等问题^[109],尚未获得中国国家药品监督管理局的全国上市批准。美国雅培公司推出的全吸收式生物血管支架 Absorb,在 2011 年取得欧盟 CE 认证并在欧洲上市,并在 2016 年成为首个获 FDA 批准上市的商用化全吸收式生物血管支架,但因市场采用率低于预期以及其存在一些技术上的局限性,雅培公司于 2017 年宣布在全球停止销售该产品^[110]。而关于 SF 基医卫纺织材料的研究转化也在进一步推进,如意大利 Silk Biomaterials Srl 公司开发的 SILKBridge 丝素复合神经导管在苏黎世大学医院的临床试验中修复了 4 例手指指神经缺损,在平均 32 个月的随访期间,所有患者恢复良好,初步证实了其人体应用安全性^[111];用于负载抗癌药物或生长因子的 SF 基微球和膜材料,通过调节结晶度控制释放动力学,已在肿瘤局部治疗和慢性创面管理中进入临床前试验^[112]。此外, Sofregen 公司的 Silk Voice[®]是首款获得美国 FDA 510(k)上市许可的 SF 基可注射软组织填充器械,用于声带内移与声带功能不全的组织填充,标志着 SF 在再生性注射材料领域实现了重大突破^[113-114]。

中国国家药品监督管理局发布并实施了 YY/T 1950—2024《组织工程医疗器械 丝素蛋白》,该标准首次系统性地规定了用于组织工程医疗器械产品的丝素蛋白的性能要求,以及标志、包装、运输和贮存等要求,并描述了相应的试验方法,适用于制备组织工程医疗器械产品的丝素蛋白,为相关产品的研发、生产和质量控制提供了权威的技术依据。另外,中国保健协会于 2024 年 11 月 1 日发布并实施了 T/CHC 3—2024《化妆品用蚕丝蛋白》。上述标准的发布与实施,预示着 SF 基材料将在多个领域有望加快标准化和产业化进程。

4.1 当前面临的主要挑战

尽管 SF 基医卫纺织材料在组织工程、药物递送与智能医疗等方向取得了显著进展,但从实验室研究走向临床与商业化仍面临多重瓶颈,主要包括:

(1) 制备与质量控制标准化不足。家蚕品系、养殖条件及提取/脱胶工艺差异易导致 SF 相对分子质量分布、纯度与二级结构显著波动,导致材料的性能在不同批次之间不稳定,可重复性降低且规模化应用受制约。

(2) 规模化与制造一致性面临挑战。当前,多数高性能 SF 材料仍处于实验室阶段,工业化放大过程中常面临流程复杂、效率偏低、成本控制困难及一致性保障不足等问题。

(3) 长期体内安全性与机制证据仍待完善。改性或复合体系可能存在试剂残留或诱发不良生物反应;同时, SF 与宿主免疫、细胞行为及局部微环境的动态相互作用机制尚需系统阐明。

(4) 监管与评价体系不健全。SF 基医卫纺织材料的行业标准、检测方法与评价流程尚不完善,该现象影响着研发到注册审评的有效衔接与转化效率。

4.2 发展建议及未来展望

针对上述瓶颈, SF 基医卫纺织材料未来可从“原料-制造-功能-评价-转化”全链条协同推进:

(1) 建立全流程标准化与可追溯体系。联合高校、企业与医疗机构构建覆盖家蚕养殖、SF 提取、加工与质控的标准化体系,推动行业规范化发展;开发多喷头静电纺丝、高速水刺等连续化生产设备,提升生产效率并优化产品性能,同时可结合分子育种与基因工程提升原料结构均一性与功能稳定性。

(2) 推动多功能复合与智能刺激响应集成。未

来, SF 基医卫纺织材料的设计应从单一结构支撑向“SF+功能因子+响应单元”的多功能集成体系转变。负载抗菌药物(如万古霉素)、抗肿瘤药物(如多柔比星)及生长因子等,实现治疗功能的协同增强;引入化学响应单元(如 pH 值、氧化还原/活性氧、酶、温度、电/光信号响应)及生物响应单元(如免疫调节因子、神经递质),实现对药物释放与组织修复过程的精准调控。

(3) 强化临床前评价与监管科学建设。现有针对大型动物的研究表明, SF 基支架与水凝胶在灭菌兼容性、血液相容性与功能有效性方面具有转化潜力^[115-116]。目前, FDA 的生物材料评价指南中, 针对天然 SF 基医卫纺织材料及其降解产物安全性评价标准有待细化, 亟需建立系统化、标准化的临床前评价流程, 重点覆盖无菌性、热原性、血液相容性、慢性毒性、体内降解行为以及货架期稳定性等关键指标, 并逐步形成适用于 SF 基医卫纺织材料的专属监管与评价标准体系。

综合来看, 家蚕 SF 基医卫纺织材料凭借生物相容性、低免疫原性、可控降解性及良好加工与改性潜力, 已成为医卫纺织领域的重要研究方向。未来研究需围绕“性能优化-功能集成-可制造性-临床证据-监管路径”开展协同突破, 并进一步关注特殊人群潜在过敏风险与长期体内安全性相关数据的系统积累。随着改性策略的不断创新与转化评价体系的逐渐完善, SF 基医卫纺织材料有望在替代部分传统合成材料、推动医卫纺织材料绿色化与智能化升级方面, 发挥更重要的作用。



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